

DETAILED ACTION

Status

Claims 1-2, 4-18, and 20-25 are pending. Claims 16-18 and withdrawn as being directed to the nonelected invention; claims 1-2, 4-15, and 20-25 are currently amended.

Amendment/Response

Receipt of the Amendment/Response filed on 21 July 2008 is acknowledged.

Specification

The objection to the specification regarding "hydrozylate" is **withdrawn in light of the arguments**, which are found to be persuasive.

Claim Rejections - 35 USC § 112

The rejection of claims 1-15 and 19-25 under 35 U.S.C. 112, second paragraph, regarding "system" is **withdrawn in light of the amendments**.

The rejection of claims 1-15 and 19-25 under 35 U.S.C. 112, second paragraph, regarding "thermoreversible" is **withdrawn in light of the arguments**, which are found to be persuasive.

Double Patenting

The provisional rejection of claims 1-2, 5-15, 19-21, and 23-25 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-6, 8-12, 17-19, and 35-37 of copending Application No. 10824919 in view of Chapdelaine et al (WO03011259) and Pearce et al (US 2003/0224090) is **maintained for the reasons of record**.

Although Applicants assert that a terminal disclaimer will be submitted, no terminal disclaimer has been made of record. Thus the double patenting rejection is maintained and considered proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1-2, 9, 12-15, and 19-21 under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al. (US'096) in view of Day et al. (US'160) and Imre et al. (HU'974) is **withdrawn in light of the amendments**. The new rejection of these claims, necessitated by amendment is described below.

The rejection of claims 1-8, 10-11, and 22-25 under 35 U.S.C. 103(a) as being unpatentable over Pearce et al. (US PG Pub '090) in view of Day et al. (US'160), Chapdelaine et al. (WO'259), and Earle et al. (US'962) is **withdrawn in light of the amendments**. The new rejection of these claims, necessitated by amendment is described below.

Claims 1-2, 4-7, 9, 12-15, and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al. (US'096) in view of Day et al. (US'160), Virgalitto et al. (WO '659), and Imre et al. (HU'974). This is a new grounds for rejection necessitated by the amendments. The prior art utilized in this rejection does not differ from that utilized in the previous rejections which have been withdrawn, but no arguments regarding these particular references were submitted in the reply filed 21 July 2008, thus the rejections are considered proper.

I. Instant Claims 1-2, 4-7, 12-15, and 20

A. Thermoreversible Alginate Gel Film with Active Agent

Zerbe teaches a film composition which comprises water-soluble polymers (which can be sodium alginate), one or more polyalcohols, and one or more pharmaceutically active agents (column1, lines 9-12; column 2, lines 18-24 and 37-44).

Zerbe does not teach thermoreversibility of the polymeric film, nor does Zerbe teach films made without the polyalcohols. However, some of the optional polymers in Zerbe's invention commonly produce thermoreversible films. In addition, Day teaches thermoreversible alginate films using acetylated alginates. It would have been obvious to one skilled in the art to combine the teachings of Zerbe and Day to produce a thermoreversible alginate film containing an active agent. One would have been motivated to do so since thermoreversibility of gel films allows for films to melt or flow at one temperature while behaving like a solid

at another temperature. Thus, in the case of Zerbe's oral films, thermoreversibility of the gels would allow the product to behave as a convenient solid in packaging, for instance, and as a flowable liquid once it reaches the temperature of the oral cavity, allowing for more rapid dispersion within the oral cavity than a film that remains a solid in the oral cavity would provide. One would have been especially motivated since Zerbe describes the desirability of rapid dissolution of the films (column 1, lines 14-16).

Regarding the polyalcohols, although the instant invention can be made with only an alginate and an active agent, and Zerbe's invention requires a polyalcohol, Zerbe explains that the polyalcohol is required to achieve a desired level of softness (column 3, lines 10-11). Therefore, it would have been obvious to one of ordinary skill in the art to remove the requirement. One would have been motivated to do so in the case where softness is not important. Furthermore, the instant invention allows for the optional addition of other ingredients, such as plasticizers, which include polyalcohols.

B. Optional additional ingredients

Zerbe also teaches the optional addition of other ingredients such as plasticizers, flavors, surfactants, sweeteners, and other excipients. Although

Zerbe does not expressly teach the addition of a second film former, bulking agents, or pH controlling agents.

Imre teaches gelled honey which contains two film-forming agents (sodium alginate and carrageenan), a bulking agent (honey contains sugars

which can serve as bulking agents), and a pH controlling agent or buffer (English abstract).

Thus it would have been obvious to combine the teachings of Zerbe, Day, and Imre to include optional additional ingredients in a thermoreversible alginate film. One would have been motivated to include a bulking agent in order to achieve the desired feel of the film. Motivation to use a pH controlling agent comes from the fact that undesirable pH can interfere with film properties, the active agent, or the taste of the film. Motivation to use plasticizers is provided because Zerbe suggests the optional inclusion of plasticizers.

C. Amount of alginate (film former)

Although Zerbe teaches the inclusion of the polymeric film former (i.e. sodium alginate) in an amount of between 20% and 75% of the final weight of the film, Zerbe does not explicitly teach the amount of alginate with regards to the dry weight of the film.

However, Zerbe does teach that in the method of making the films, the mixture is coated onto a suitable material and then dried to create the final film (column 3, lines 55-56). Therefore, in the event that Zerbe's films are fully dried, the instantly claimed ranges of claims 1 and 4-7 are fully encompassed by or significantly overlapping with Zerbe's ranges for the amount of film former (alginate) based on dry weight. In the event that Zerbe's final films still contain some water, it is clear that the instantly claimed ranges of claims 1 and 4-7 are fully encompassed by or significantly overlapping with Zerbe's ranges for the

amount of film former (alginate) based on dry weight, since the amount of water left in the "dried" films would be very small. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to alter the amount of film former (alginate) based on the desired properties of the final film. One would have been motivated to do so in order to effect desired properties on the film, such as dissolution behavior, film feel, and film taste. Additionally, it would have been obvious to one of ordinary skill in the art to vary the amounts of the ingredients because Virgalitto teaches variation of the amounts of the ingredients based on the desired properties of the film and the nature of the other ingredients in the film (page 6, fifth paragraph).

D. Break force strength

Zerbe does not expressly describe the strength of the gel film compositions, however, Day discusses the increased flexibility and strength of acetylated alginates that form strong thermoreversible gels (column 2, lines 38-40) and Virgalitto teaches that the choice of materials to make the film is dependent on the desired strength of the film and further asserts that the gel films are of sufficient mechanical strength to be handled without special precautions. Thus it would have been obvious for one of ordinary skill in the art to create gel films with substantial strength using alginates (and also alginates in combination with other strong film formers such as carrageenans) in order to create films that can survive handling and storage. Additionally, the obvious compositions Zerbe and Day would be expected to have the same break force

strengths as those claimed in Applicants' invention. Furthermore, the high and low break force strengths claimed are inherent properties of the claimed film compositions, particularly regarding the optional addition of plasticizers. Plasticizers increase film strength and reduce breaking of gels (Virgalitto, page 5, third paragraph). Thus the instantly claimed break force strengths are rendered inherent and obvious.

II. **Instant Claim 9**

Zerbe teaches that the polymers can be used either alone or in mixtures (column 2, lines 41-42), thus indicating that a film composition with only alginate as the film former is obvious to one skilled in the art over the teachings of Zerbe. One would have been motivated to utilize only one film former, such as sodium alginate, since Zerbe suggests sodium alginate as a film former and suggests that the film formers may be used alone.

III. **Instant Claim 21**

Zerbe teaches the optional addition of other ingredients such as flavorings (column 2, lines 21-23). Zerbe does not teach solids content.

Imre discloses a preparation of gelled honey with sodium alginate, carrageenan, and a buffer (English abstract). The honey itself contains fructose, a known plasticizer, as well as other sugars, which are known to serve as bulking agents and honey is also known to have flavor and therapeutic properties, making it a flavorant and an active agent in the gel. The solids are adjusted to 62% to 72% (Imre English abstract). It would have been obvious to one of

ordinary skill in the art to add a flavoring to the gel composition since this would improve the taste or mask a medicinal taste in cases where the film would be used orally. It would also have been obvious to one of ordinary skill in the art to adjust the solids content of the gel because, as Virgalitto states, a high solids content accelerates drying of the film (page 6, 4th paragraph) and Zerbe explains that the film thickness is dependent upon the solids content (column 4, lines 1-2).

Claims 1-2, 4-8, 10-15, 20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearce et al. (US PG Pub '090) in view of Day et al. (US'160), Tobacman, Virgalitto et al. (WO '659), and Chapdelaine et al. (WO'259). This is a new grounds for rejection necessitated by the amendments. The prior art utilized in this rejection does not differ from that utilized in the previous are rejections which have been withdrawn, but no arguments regarding these particular references were submitted in the reply filed 21 July 2008, thus the rejections are considered proper.

I. Instant Claims 1-2

A. Thermoreversible Alginate Gel Film

Pearce teaches orally soluble edible films comprised of water and a film forming agent which can be alginates, carrageenans, derivatives or combinations thereof, and other hydrocolloids (page 1, paragraph [0026]; page 2, paragraphs [0028], [0029], and [0032]).

Pearce does not teach thermoreversibility.

Day teaches strong thermoreversible gels made from acetylated alginates (column 2, lines 36-40). Thus it would have been obvious to one of ordinary skill in the art to make a thermoreversible alginate gel. Motivation to use alginates is provided because other hydrocolloid film formers, such as carrageenans, are potentially harmful (Tobacman). Motivation to achieve thermoreversibility lies in that it allows gel films to be more easily poured and cast. One would have been motivated to achieve thermoreversibility since thermoreversibility of gel films allows for films to melt or flow at one temperature while behaving like a solid at another temperature. Thus, in the case of Pearce's oral films, thermoreversibility of the gels would allow the product to behave as a convenient solid in packaging, for instance, and as a flowable liquid once it reaches the temperature of the oral cavity, allowing for more rapid dispersion within the oral cavity than a film that remains a solid in the oral cavity would provide.

B. Addition of Active Agent/Pharmaceutical

Pearce teaches that the gel film may contain additional ingredients such as a pharmaceutically active agent (page 9, paragraph [0137]). Thus it would have been obvious to one of ordinary skill in the art to include an active agent, more specifically a pharmaceutical, in the gel composition. One would have been motivated to do so since Pearce suggests the use of a pharmaceutical in the oral film, and since doing so provides an opportunity for delivery of the active substance in the oral cavity rather than in the gastrointestinal tract.

C. Optional additional ingredients

Pearce's film may also contain other additives for plasticizing (such as glycerin), a bulk filling agent (such as microcrystalline cellulose), stabilizers (such as carrageenan), flavorings, and pharmaceutically active agents (page 3, paragraphs [0048], [0052], and [0058]; page 9, paragraph [0137]). Pearce also teaches that the gel film compositions may be a combination of more than one film former (Pearce, page 2, paragraph [0028] and [0032]).

Pearce does not teach the optional addition of a pH-controlling agent.

However, Chapdelaine teaches the optional addition of a pH-controlling agent in edible film formulations (page 6, line 22). Thus the optional addition of ingredients such as plasticizers, bulking agents, a second film former, and a pH controlling agent would have been obvious to one of ordinary skill in the art. Motivation to include plasticizers, bulking agents, and a second film former is provided in that Pearce suggests the optional inclusion of such ingredients. Motivation to include the pH controlling agent is provided in that Chapdelaine describes that such an agent can control breath freshness and perform oral cleansing (page 6, lines 19-22).

D. Amount of alginate (film former)

Pearce teaches that the film forming agent comprises 10% to 90% of the dry weight of the film (page 2, paragraph [0034]. Pearce does not expressly teach a percent by weight of the dry film formers. Chapdelaine teaches that the hydrocolloid constitutes 30% to 40% of the dry weight of the film (claims 18), and

further provided compositions wherein the alginate comprises 12%-31% of the dry weight of the gels (examples 1-10). In regards to the instant claims drawn to the percent of alginate among only the dry film formers, Chapdelaine also teaches a composition wherein alginate is 50% of the two hydrocolloid film formers (example 10). These prior art compositions are significantly overlapping with the ranges claimed by the instant invention. "In the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior Art' a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)." Furthermore, it would have been obvious to one of ordinary skill in the art to vary the amounts of the ingredients because Virgalitto teaches variation of the amounts of the ingredients based on the desired properties of the film and the nature of the other ingredients in the film (page 6, fifth paragraph). Additionally, these percentages are an optimization of range and "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus the ranges claimed by Applicants in the instant invention are rendered obvious.

E. Break force strength

Pearce does not expressly describe the strength of the gel film compositions, however, Day discusses the increased flexibility and strength of acetylated alginates that form strong thermoreversible gels (column 2, lines 38-

40) and Virgalitto teaches that the choice of materials to make the film is dependent on the desired strength of the film and further asserts that the gel films are of sufficient mechanical strength to be handled without special precautions. Thus it would have been obvious for one of ordinary skill in the art to create gel films with substantial strength using alginates (and also alginates in combination with other strong film formers such as carrageenans) in order to create films that can survive handling and storage. Additionally, the obvious compositions created from the teachings of Pearce and Day would be expected to have the same break force strengths as those claimed in Applicants' invention. Furthermore, the high and low break force strengths claimed are inherent properties of the claimed film compositions, particularly regarding the optional addition of plasticizers. Plasticizers increase film strength and reduce breaking of gels (Virgalitto, page 5, third paragraph). Thus the instantly claimed break force strengths are rendered inherent and obvious.

II. Instant Claim 22

The choice of carrageenans as second film formers is obvious, as discussed above. The viscosity of the carrageenan solution is an inherent property that is inseparable from that solution and is therefore obvious.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pearce, Day, Tobacman, Virgalitto, and Chapdelaine as applied to claim 1 above, and further in

view of Glicksman (IDS 11/14/2005). The prior art utilized in this rejection does not differ from that utilized in the previous are rejections which have been withdrawn, but no arguments regarding these particular references were submitted in the reply filed 21 July 2008, thus the rejections are considered proper.

I. Instant Claim 10

Pearce teaches the possible use of carrageenans as film formers and also suggests that the gel film compositions may be a combination of more than one film former (Pearce, page 2, paragraph [0028] and [0032]), but does not expressly show alginates in combination with carrageenan.

Chapdelaine teaches a gel created with a combination of carrageenan and alginate as the hydrocolloid film formers (example 10), and Glicksman notes that typical carrageenan contains 60% kappa carrageenan (page 218, last paragraph). Glicksman also indicates (in Table III) that kappa carrageenan gels most strongly with potassium ions, rather than lambda carrageenan (which does not gel) and iota carrageenan (which gels most strongly with calcium). It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize kappa carrageenan. One would have been motivated to do so since calcium is not required to make a strong gel network with kappa carrageenan and calcium provides the best potential for alginates to gel in a thermo-irreversible manner, so it should be avoided when a thermo-reversible gel is desired.

Claims 11 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearce, Day, Tobacman, Virgalitto, and Chapdelaine as applied to claim 1 above, and further in view of Earle et al. (US'962). The prior art utilized in this rejection does not differ from that utilized in the previous are rejections which have been withdrawn, but no arguments regarding these particular references were submitted in the reply filed 21 July 2008, thus the rejections are considered proper.

I. **Instant Claim 11**

Pearce teaches the optional addition of glycerin plasticizers (Pearce, page 3, paragraph [0045]). The obviousness of the addition of kappa carrageenan is discussed above. Pearce also discusses the optional use of a bulk filling agent such as microcrystalline cellulose (Pearce, page 2, paragraph [0042]).

Pearce does not expressly discuss starch hydrolysates.

Earle teaches the use of corn syrup as a bulking agent in an alginate-based edible film (column 4, lines 5-12), and corn syrup is a starch hydrolysate. Thus the gel composition with a glycerin plasticizer, kappa carrageenan as a second film former, and a bulking agent such as microcrystalline cellulose or a starch hydrolysate is rendered obvious. One would have been motivated to add a glycerin plasticizer, kappa carrageenan as a second film former, and a bulking agent such as microcrystalline cellulose because Pearce suggests the addition of these ingredients. One would have been motivated to add a starch hydrolysate (hydrozylate) bulking agent such as corn syrup since, in addition to providing

bulk, it would have the added benefit of sweetening the film without adding extra ingredients. One would reasonably expect success since Earle utilizes corn syrup in an alginate-based edible film.

II. Instant Claim 23

Pearce allows for the optional addition of other ingredients such as plasticizers, but does not expressly teach a gel composition with alginate and without a plasticizer. Since the addition of plasticizers is optional, it would be obvious for one of ordinary skill in art to exclude a plasticizer from the gel composition. Earle also suggests alginate compositions which do not require plasticizers (column 3, lines 65-68; and column 4, lines 1-15). The motivation to exclude a plasticizer would come from the desire to have a film that breaks rather than stretches, or is of a harder consistency, depending on the intended use of the film.

III. Instant Claims 24-25

Pearce teaches the optional use of a bulking agent (page 2, paragraph [0035], [0041], and [0042]). Thus it would have been obvious to one of ordinary skill in the art to utilize a bulking agent. One would have been motivated to use a bulking agent not only because Pearce suggests its use, but also in order to improve the texture of the film; Pearce notes that using a bulking agent reduces the "slimy" texture of pullulan-free gels (page 2, paragraph [0035]).

Pearce does not expressly teach the use of corn syrup. Earle teaches the use of corn syrup as a bulking agent (column 4, lines 5-12). Thus it would have

been obvious to one of ordinary skill in the art to utilize corn syrup as a bulking agent. Since corn syrup is also a sweetener, one of ordinary skill in the art would be motivated to use corn syrup as a bulking agent because it can also sweeten the film for better taste in oral consumption. One would reasonably expect success since Earle utilizes corn syrup in an alginate-based edible film.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH S. CAPAN whose telephone number is (571)270-5235. The examiner can normally be reached on Mon-Thurs 8:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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